AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT	1. CONTRACT ID CODE	PAGE OF PAGES

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
PR-NC-05-10097/0002	05/12/05	PR-NC-05-10097	

6. ISSUED BY CODE	7. ADMINISTERED BY (If other than item 6) CODE
Environmental Protection Agency RTP Procurement Operations Division (D143-01) 4930 Page Road Durham, NC 27703	Not Applicable.

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)	(✓)	9A. AMENDMENT OF SOLICITATION NO.
To All Offerors/Bidders.		PR-NC-05-10097
	✓	9B. DATED (SEE ITEM 11) 04/26/05
		10A. MODIFICATION OF CONTRACT/ORDER NO.
		10B. DATED (SEE ITEM 13)
CODE FACILITY CODE		

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

[X] The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers [ ] is extended, [X] is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning 1 copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

(✓)	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	c. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor [ ] is not, [ ] is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

The purpose of this amendment is to modify the language in Clause M.3, paragraph (b) and add paragraph l to the Statement of Work, Attachment 1.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
		LENORA HILLIARD	
15B. CONTRACTOR/OFFEROR	15C DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(Signature of person authorized to sign)		(Signature of Contracting Officer)	

NSN 7540-01-152-8070 30-105 STANDARD FORM 30 (REV 10-83)
PREVIOUS EDITION UNUSABLE Prescribed by GSA
FAR (48 CFR) 52.243

AMENDMENTS TO THE SOLICITATION

1. The Section M clause entitled "EVALUATION FACTORS FOR AWARD (EPAAR 1552.215-71) (AUG 1999)" has been modified. The text is as follows:

(a) The Government will make award to the responsible offeror(s) whose offer conforms to the solicitation and is most advantageous to the Government cost or other factors considered. For this solicitation, technical evaluation criteria are significantly more important than cost or price.

(b) Technical Evaluation Criteria:

The evaluation of technical proposals will be based upon the following **seven** evaluation criteria: (1) Demonstrated Understanding of and Technical Responsiveness to the RFP (25 points); (2) Adequacy of QA Management Plan (10 points); (3)Adequacy of Proposed Subcontracting Plan (10 points); (4) Safety (10 points); (5) Past Performance (25 points); (6) Personnel Qualifications (15 points); and (7) Transition Plan (5 points). In order to expedite EPA's evaluation, the technical proposal should be submitted either as **seven** stand alone documents: a separate document responding to each of the technical evaluation criteria and a brief introduction outlining company makeup, location, and any other relevant information or a single binder with each of the technical evaluation criteria tabbed and easily identifiable and a brief introduction outlining company makeup, location, and any other relevant information. While EPA does not wish to place any formal restrictions on the length of the technical proposal, as a guide, **it is suggested that offerors limit their responses to each individual criterion to around 15 pages.** Offerors will not be penalized if the number of pages slightly exceeds the suggested number. However, the technical proposal should be brief and concise. A lengthy, voluminous proposal is viewed as being more difficult to evaluate, and specific evaluation points may be lost in the verbiage. Specific instructions for responding to each of the evaluation criteria are listed below.

Technical proposals will be evaluated against the following criteria on the basis of evidence contained in the technical proposal:

	CRITERION	WEIGHT
(1)	Demonstrated Understanding of and Technical Responsiveness to the RFP:	25
	a. Proposal reflects understanding of systems maintenance, upgrade and operations issues as described in this RFP.	
	b. Proposal reflects understanding of issues associated with exposing human subjects under research conditions.	
	c. Proposal reflects understanding of air pollution chemistry, sampling	

and monitoring as applicable to human exposures.

(2) Adequacy of QA Management plan. 10

(3) Adequacy of Proposed Subcontracting Plan. 10

The offeror shall submit the information required by the clause, FAR 52.219-9, entitled "Small Business Subcontracting Plan". In the Subcontracting Plan, the offeror shall describe its plan for subcontracting with small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business concerns, small disadvantaged business, and women-owned small business concerns under this contract.

(4) Safety: 10

a. Demonstrated understanding of the importance of safety throughout all critical and non-critical areas of work as specifically defined in this requirement.

b. General and specific approaches that will be taken to assure that the health, safety and welfare of research subjects will be maintained.

(5) Past Performance 25

Demonstrated successful past performance of the offeror and any major subcontractors as evidenced by information provided by the clients in the past performance questionnaire concerning the list of contracts and subcontracts completed during the past three years and those in process for similar work.

a. Quality of products and services provided in previous contracts of similar size and complexity. 10

b. Timeliness in providing products and services 5

c. Responsiveness to correcting performance problems 5

d. Overall customer satisfaction 5

(6) Personnel Qualifications 15

Demonstrated capability of proposed key personnel to perform the Statement of Work as evidenced by work experience, educational background, and versatility. Demonstrated ability of the contractor to recruit and retain qualified personnel.

a. Technical experience of personnel relevant to project.

b. Academic and technical education of key personnel relevant to project.

c. Flexibility of proposed key personnel and other personnel to work in multiple disciplines and ability of the contractor to recruit and retain qualified personnel.

(7) Transition Plan 5

Basis for evaluation is the demonstrated adequacy and efficiency of the Transition Plan to affect a smooth transition so that down time is minimized. The offeror shall describe the methodology to be used to affect the transition.

TOTAL 100

2. The attachment entitled "STATEMENT OF WORK" has been modified. The text is as follows:

STATEMENT OF WORK
FOR
OPERATION, MAINTENANCE AND MODIFICATION OF THE HUMAN STUDIES FACILITY

A. GENERAL REQUIREMENTS

1. Background. The Contractor shall provide experienced, appropriately licensed and certified personnel, shop and office facilities, supplies, instrumentation, spare parts and test equipment to operate, maintain, and modify seven human exposure chambers and their associated support systems, two aerosol particle concentrators and exposure chambers, two non-exposure test rooms and four in-vitro exposure chamber pairs and their support systems. The contractor shall also be responsible for maintenance and modification of the bio-medical equipment in the Medical Station, but not its operation. The support systems include a high capacity clean air supply system, associated computers, pumps, filters, fans, heated and chilled glycol-water supply equipment, a large capacity heat exchange system for generating 450° F oil, electrical distribution equipment and wiring, pollutant generation and control equipment and associated computers, seven computer controlled individual air handling units providing custom conditions to the human exposure chambers, and medical gas and vacuum generation and delivery systems.

All air supply systems are operated by a commercial Andover BAS control system. Air pollutants are generated and monitored by the Environmental Exposure System (EES), running custom designed software (called the Pollutant Control System, or PCS) on COMPAC Alpha equipment using the Open VMS operating system. The EES both controls and records the exposure conditions used for

each protocol.

The contractor shall also maintain, modify and sometimes operate various small scale exposure systems. These systems are usually developed by investigators for delivering non gaseous materials to subjects as part of exposures that do not involve the entire body. The exposures are usually of short duration and target endpoints that aren't reached through regular inhalation exposures, or involve such small quantities of pollutants that a full chamber can't be used. Typically, these systems function independently of the aforementioned exposure chambers, and are made up a of a number of bio-medical, electrical and mechanical components. These can include pneumotachs, nebulizers, computers, transducers, valves and switches.

2. All the facilities to be operated and maintained are located in the Human Studies Facility (HSF) on the Medical School Campus of the University of North Carolina at Chapel Hill, North Carolina, at 104 Mason Farm Road.

3. Contractor staff shall periodically be required to modify and upgrade selected systems to ensure that state of the art capability is maintained at the facility. They shall also be required to design, acquire, install and maintain new equipment and instrumentation.

The contractor shall also provide operational assistance and support for exposure studies that use small scale exposure systems which are independent of the exposure chambers referenced above. Examples of these include aerosol delivery devices, such as nebulizers, and dermal exposure systems. Contractor staff shall be responsible for the hardware and software elements of exposure equipment; EPA or EPA approved staff will conduct all hands-on interactions with volunteers.

4. The contractor shall provide preventative maintenance, repairs, operation services, limited overtime services, and support services, such as periodic cleaning of the exposure chambers. All services shall be in accordance with this Scope of Work (SOW). Strong emphasis shall be placed on identifying and correcting potential problems before they disrupt research operations.

5. The contractor shall maintain assigned machinery spaces, storerooms and other work areas in a clean and orderly manner. Following work in any area, contractor staff shall daily remove all debris, clean as appropriate and properly store equipment and material. All facility operations, including disposal of all hazardous materials and wastes, shall be in accordance with applicable UNC and EPA policies.

6. The contractor shall keep records and inventories of all equipment, supplies, parts, maintenance schedules and records of activity, chamber operating conditions, malfunctions and corrective actions taken, other problems, and overall records of their operations and actions, including written operating plans. All contract related records shall be available to the Agency upon request.

7. The contractor shall provide reports of work as specified in Appendix 1. All reports should be in hard copy format, and electronic versions supplied upon request.

B. DEFINITIONS

1. "Operations" include the daily and other periodic starting, stopping, adjusting, inspecting, lubricating, calibrating and troubleshooting of the mechanical, electrical, utility, safety, and biomedical equipment necessary to conduct human and cell exposure studies at the Human Studies Facility. Operations further include generating and monitoring the desired pollutant concentrations specified in each research protocol for each exposure, whether conducted in the exposure chambers or using other exposure equipment. Overall, all contractor efforts shall be directed to supporting exposures of trained test volunteers to carefully monitored levels of pollutants, under conditions approved by designated Institutional Review Boards (IRBs). Specific responsibilities and expectations are identified in Task 1.

2. "Maintenance" is work required to perform equipment repairs, and includes "preventive maintenance," the routine inspection and checking of equipment, followed by the actions necessary to prevent breakdowns. Repairs include all work required to put an item of equipment or a system back into service after a breakdown or failure. The objective of these activities is to ensure that exposure studies are carried out safely and reliably, without unscheduled disruptions attributable to equipment problems. Specific responsibilities and expectations are identified in Task 1.

3. "Modifications" are the system changes and upgrades necessary to ensure that the best and most modern equipment available is used in conjunction with exposure studies. New techniques, instrumentation and system components shall be incorporated into existing systems and equipment to ensure that Human Studies Facilities reflect the state of the art. Design, acquisition and installation of new equipment and instrumentation may also be required. Specific responsibilities and expectations are identified in Task 5.

C. TASK 1- SYSTEM OPERATION AND MAINTENANCE

This task provides for the operation and maintenance of the systems supporting the human exposure and in vitro chambers, subject test rooms, the Medical Station, and their support systems. A list of all major items of equipment is provided in Attachment 3, Asset/Equipment Inventory, for each of the major subsystems. The Contractor shall provide all test equipment required to perform the contract. The major systems and subsystems to be operated and maintained are listed below.

1. **Exposure Air Supply System**. The exposure air supply system is made up of three custom configured air handling units (or "skids") which bring in outside ambient air, and filter and dehumidify it for use as supply air to the exposure chambers. The three skids each supply up to 5,500 cubic feet per minute of clean, dry air (temperature 10 C, -10 C dewpoint) to a common plenum. Each skid consists of a supply fan, cooling and heating coils, a desiccant wheel dehumidification unit, air filters and air scrubbers. Dust and HEPA filters remove particles down to sub-micron sizes. Scrubber filter systems using carbon chemisorbent and a catalytic oxidizer remove gas phase air contaminants. A gas fired, six million Btu/hr heat exchange unit supplies heated oil (up to 450 °F) for the catalytic units.

The seven individual air handlers for the exposure chambers take their supply air from the common clean air plenum. Each chamber air handler contains a supply fan, steam grid humidifier, cooling and heating coils, and controls. Exhaust fans for each chamber are located in a penthouse on the roof of the

research tower building. The HSF has its own dedicated steam to steam generator supplying RO/DI steam to the chamber humidifiers, and a two-loop glycol chiller system. Both systems are respectively supplied by steam and chilled glycol from UNC plants. All of the above systems and equipment are operated by the central Andover BAS control system.

2. **Pollutant Delivery and Control System**. The Pollutant Delivery and Control System regulates the concentration of ozone, carbon monoxide, nitrogen dioxide, sulphur dioxide, VOCs and other possible pollutant gases, injected into the inlet air stream of the human exposure and in vitro chambers. The system delivers the contents of bottled gases, or gases produced on site to the input clean air supply of each chamber. Once delivered, the system continuously monitors concentrations in the chambers using dedicated glass sampling lines and analyzers. The Pollutant Delivery and Control System operates in conjunction with the Exposure Air Supply System (EASS) described above, and consequently, is controlled centrally using the analyzers monitoring the chambers. Automated calibration, data logging and alarm features are also incorporated.

3. **Aerosol Concentrator Exposure Systems**. The facility has two vacuum operated aerosol concentrator exposure systems. The first concentrates coarse particles of from 2.5 to 10 um-MMAD and is made up of a high volume size selective inlet (SSI), a two-stage virtual impactor, a diluter/conditioner, a single person human exposure chamber, and inlet and outlet aerosol monitoring equipment. During operation, ambient air from the roof of the chamber wing of the HSF enters the high volume SSI where particles larger than 10 micrometers in mass median aerodynamic diameter (10.0 um-MMAD or PM 10.0) are inertially separated from the air stream. The remaining flow with particles of less than 10.0 um-MMAD enters the two-stage, slit type virtual impactor which inertially concentrates particles larger than 2.5 um. Particle concentrations average approximately 60 times ambient levels. The concentrated aerosol stream is then diluted with clean, conditioned air before entering the human exposure chamber on the floor below, where internal atmospheric pressure ranges from negative .5 to negative 1.5 inches of water. Instrumentation used in this system includes: total filter samplers, Aerosol Particle Sizers, and DataRam particle counters.

The second concentrator system concentrates fine and ultra fine particles of 2.5 um-MMAD and smaller. It consists of a high volume, size selective inlet, steam generation and control equipment compatible with reagent grade water, refrigeration unit and condenser, two stage virtual impactor, and heated particle reshaping unit. Its principles of operation are the same as the coarse concentrator, with the addition of steam moisture followed by cooling in order to grow ultra fine particles to a size which allows for inertial concentration. Particle concentrations average 40 to 50 times ambient levels and atmospheric pressure in the chamber ranges from negative 20 to negative 25 inches of water during exposures to ultra fine particles. Instrumentation includes Condensation Particle Counters and Scanning Mobility Particle Sizers.

4. **Laboratory and Medical Air and Vacuum Systems**. Laboratory grade compressed air is supplied to both the human exposure chambers and individual laboratories by a 150 hp., 618 cfm compressor and a 75 hp., 292 cfm compressor. Compressed air is then processed using two Zeks units in a lead/lag configuration. Air is heatless dried, filtered and scrubbed using

Nomonox catalyst. Air for laboratory applications is then routed to regulators for distribution throughout the facility. Air for medical grade applications receives further filtration and processing, as well as dewpoint and hydrocarbon content monitoring, to achieve NFPA 99 standards for breathable air.

Laboratory air for instrumentation calibration is processed using an AADCO pure air generator. Incoming air is dried, filtered and scrubbed using a heated catalyst. The finished air contains less than .001 ppm ozone, sulfur and nitrogen compounds, and less than .005 ppm methane and other carbon compounds.

Vacuum for operating the aerosol concentrator systems is supplied by a 50 hp Quincy oil flooded, rotary screw pump, which produces 682 scfm at atmospheric pressure, 400 scfm at -15 inches mercury. Laboratory and medical vacuum are supplied by 2 Nash water seal pump systems in a lead/lag configuration, supplying 30 scfm at -20 inches mercury.

5. **In-Vitro Chamber Systems**. The four sets of In-Vitro chambers consist of small exposure chamber pairs housed in constant-temperature incubators. One chamber of each pair functions as a cell culture exposure chamber for the same air pollutants used in the whole body chambers. The other chamber functions as a clean air reference. The chambers measure 12 x 12 x 16 inches high. Each is housed in a temperature controlled box which operates at a slightly negative air pressure with respect to the room. Each chamber has one-pass air flow with the air generally moving from top to bottom at the rate of 20 L/min. Pollutants are produced and delivered to the chambers using a computer controlled system of compressed gas cylinders and gas generators. Analyzers modified to operate in a high temperature and humidity environment measure the pollutant concentrations in the chambers and provide information to the computer program that controls pollutant delivery.

6. **Medical System**. This task includes maintenance of biomedical equipment located in two Subject Test Rooms, the Medical Station (including exam and special procedures rooms), and other specified locations throughout the building, as well as equipment associated with the human exposure chambers. The Contractor shall be responsible for calibration, maintenance, emergency repairs, electrical safety and inventory control of this equipment, but not its operation. Examples of the equipment in use include bronchoscopes, a SpaceLabs centralized EKG monitoring system, and various pulmonary function testing equipment, such as spirometers and plethysmographs.

7. **Small Scale Exposure Systems**. These systems are used by investigators to address particular exposure needs not amenable to being conducted in the chambers referenced above. These systems typically shall not require whole body exposures to air pollutants, but shall involve more limited exposures such as the skin on a limb, or inhalation of specifically formulated particles or other agents.

With the exception of #6 above, the Medical System, operation and maintenance conducted under this task shall include all of the following seven activities. The Medical System shall receive only preventive maintenance, calibration and emergency repairs.

1. **Preventive Maintenance.** Documented preventive maintenance procedures and schedules shall be followed for each item of equipment listed in Appendix 2. The Contractor shall keep a sufficient supply of spare parts and consumables

to ensure that all preventive maintenance can be carried out in a timely manner. The Contractor shall employ flexible schedules since all preventive maintenance must be performed between human studies experiments. The schedules shall incorporate the use of nights, weekends and Government holidays when required to maximize the use of system down time. The Contractor shall maintain records of the preventive maintenance performed during the contract period of performance. At a minimum, the records must include the equipment property number, the date the maintenance was performed, the work performed and who performed the maintenance. Schedules and procedures shall be reevaluated from time to time and modified as required to minimize facility downtime and maximize effectiveness and safety.

2. **Calibration.** Selection of calibration tests shall depend on the device being calibrated. The types of calibration required include the following general categories:

a. Static calibration to determine the response of the system to a series of non-varying test signals resulting in a calibration curve, e. g., output voltage vs. magnitude of input signal.

b. Dynamic calibration to determine device phase and frequency response.

c. System integrity checks to ensure that a device operates properly under actual conditions of use.

The Contractor shall calibrate all transducers associated with the systems in accordance with a maintenance schedule to be developed jointly with EPA staff.

The Contractor shall maintain suitable records of all calibrations made during the contract period of performance. Calibration schedules shall maximize use of system down time and not affect routine research operations. Where possible, all calibration standards should be traceable to the National Institute of Standards and Technology or derived from accepted values of physical or chemical constants. Calibration of medical equipment shall be performed or supervised by appropriately qualified staff.

3. **Emergency Repairs.** The Contractor shall provide on-site personnel who shall be capable of repairing a human exposure system, training room, medical station, small scale exposure, or in vitro chamber subsystem failure within two hours of notification. Repair procedures may require that Contractor personnel enter the environmental chamber during an exposure experiment when gaseous, VOC, or aerosol pollutants are present. The Contractor shall maintain records of emergency or unscheduled repairs made during the contract period of performance. At a minimum, the records must include the property number, the date the repair was performed, the work performed and who performed it. These records shall be reviewed periodically and used to increase preventive maintenance frequency or modify maintenance procedures.

4. **Daily System Inspection.** The Contractor shall inspect critical systems each research day to determine that the systems are functioning within specifications. Special emphasis shall be placed on system components which could compromise the safety of operators or subjects. Documented evidence of these inspections shall be maintained through the use of Daily Check Sheets which are filed after their completion, and maintained for the contract period of performance.

5. **Subject Exposure Log.** The Contractor shall maintain and file, for the contract period of performance, a Subject Exposure Log. This log shall be used to record all subject chamber exposures. At a minimum, the log shall include

the date, times, subject number, protocol ID, desired pollutant levels, signatures of system operators, and notes of any unusual events during exposures.

6. **Inventory Control.** The Contractor shall provide an inventory control system for all materials provided to the contractor, as well as those acquired under the contract. Reports of inventory shall be available when requested by the EPA Project Officer and others designated by the contracting or project officer.

7. **Housekeeping.** The Contractor shall be responsible for ensuring the overall cleanliness, organization and appearance of all areas and equipment under his purview. This includes trash removal, sweeping, vacuuming, mopping, wet wiping and scouring of floors, walls, windows, plumbing fixtures, equipment and work surfaces as needed and appropriate. The Contractor shall only perform housekeeping for the exposure chambers and related work areas that are used for the performance of this contract and not being serviced by the current EPA custodial contractor.

D. TASK 2 - COMPUTER OPERATIONS AND DATA MANAGEMENT

The Contractor shall be responsible for operating and maintaining the computer systems associated with the systems listed in item 1 below. Systems are understood to include computer hardware and software, data management, and applications software. This task specifically excludes system upgrades which are covered in Task 5.

1. **Computer Hardware Operation and Maintenance**, The Contractor shall be responsible for the operation, preventive maintenance, backup and repair of computers and their associated peripheral equipment used in the Exposure Air Supply System, the Pollutant Delivery and Control System, Small Scale Exposure Systems, the In Vitro Chamber System, the Aerosol Concentrator Exposure Systems, bio medical equipment, and the associated database machines. All equipment is listed in Attachment 3. Maintenance of network hardware necessary for these systems is also included. Other computers and systems may be added as new exposure systems and equipment are developed. Operation of these systems shall include calibration, set up for data collection, review of collected data and PI notification of discrepancies.

2. **Data Management.** The Contractor shall maintain the Exposure Facility database. The technical description of the database is contained in the Human Studies Database Data Dictionary, document number 68D00207--0093DDDBS, Attachment 4. This includes the following records and databases.

Calibration Data. Calibration constants derived from the latest calibration procedures.

Exposure Data. Pollutant concentration profiles.

Data Validation. Data validation is defined as accepting or rejecting data based on criteria defined by the Agency. The Contractor shall be responsible for the validation of all data collected or generated by the Contractor, including the pollutant delivery and control system, calibration and off-line data generated from sources such as small scale systems or filter weighing . A summary of the data validation process is incorporated into the contract in the Quality Assurance Project Plan.

Data Reporting. The contractor shall be responsible for running and developing programs that shall provide data reports to EPA describing the

performance of the Pollutant Delivery and Control Systems.

3. Software Maintenance. The Contractor shall be responsible for maintaining system software, application software, and support programs. The Contractor shall also procure and maintain appropriate software licenses for systems maintained under this contract.

E. TASK 3- Quality Assurance

The Contractor shall perform the necessary quality assurance (QA) and quality control (QC) activities to meet the quality assurance objectives for the contract's Statement of Work (SOW). The Contractor, as part of its proposal, shall submit a Quality Management Plan for the SOW as prescribed in the agency document EPA QA/R-2 entitled "EPA Requirements for Quality Management Plans".

Within 30 calendar days after award of the contract, the Contractor shall review the present QA Project Plan (QAPP) for the SOW entitled " Operation, Maintenance, and Modification of Human Studies Facilities Quality Assurance Project Plan Document Number 68D00207-0013QAPP and submit a critique to the Project Officer. If modification or additional development of the QAPP is required, the Contractor shall prepare the required revision within 30 calender days of notification and submit it to the Project Officer for approval. Clarifications of the revised QAPP shall be resubmitted within 30 calender days of notification of the revisions by the Project Officer. Upon Project Officer approval of the revised QAPP, it shall be implemented by the Contractor. Until that time, procedures shown in Document Number 68D00207-0013QAPP shall be followed.

The Contractor shall modify the QAPP throughout the period of performance of this contract to meet new requirements identified by the Contractor or by EPA and shall submit proposed modifications for Project Officer approval. At a minimum, the Contractor shall review the plan annually and submit written certification of that review to the project officer.

The QAPP shall be prepared as prescribed by the most recent version of agency document EPA QA/R-5 entitled "EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations" and by the most recent version of agency document EPA QA/G-5 entitled "EPA Guidance for Quality Assurance Project Plans". QA guidelines and requirement documents including EPA QA/R-2, EPA QA/R-5 and EPA QA/G-5 are available at the following address: http://www.epa.gov/quality/qatools.html . These documents are in the ADOBE acrobat PDF format.

The Contractor shall submit Quality Assurance Reports as separate sections of its progress reports. In addition, the Contractor shall accommodate EPA-conducted independent assessments of the Contractor's QA/QC program throughout the contract's period of performance.

F. TASK 4 - SAFETY

The contractor shall operate and maintain all the equipment and systems under its purview in a manner which ensures the safety of subjects and system operators. Major aspects of the required safety program are identified below.

1. Test Subject Safety. The Contractor shall ensure the general safety

of test personnel, including test subjects, by compliance with the requirements specified in the facility safety manuals specified in Section 2 of this TASK 4. In addition, the applicable Department of Health, and Human Services (DHHS) regulations for conducting Biomedical Research on human subjects apply. As applied to EPA, these regulations are spelled out in EPA Order 1000.17, change A1, Policy and Procedures on Protection of Human Research Subjects in EPA Conducted or Supported Research. This document can be found at http://www.epa.gov/oamrtpnc/forms/index.htm. Specific subject safety in exposure facilities shall be ensured by the following provisions:

- Two-way voice communication,
- Direct visual contact, including closed-circuit television, and
- ECG monitoring.

Contractor personnel shall be trained in the use of emergency treatment equipment which include an on-site defibrillator, crash cart, respirator, etc.; however, the Contractor will not be responsible for administering emergency treatment to test subjects. Contractor on-site biomedical personnel shall also be trained in the use of the self-contained breathing apparatus equipment for accomplishing rescue under adverse conditions, but the contractor will not be responsible for conducting the actual rescue operation. The contractor shall be responsible for monitoring and maintaining preset environmental parameters within the study chambers but will not be responsible for the physical condition of the human subjects in the test chambers. Although the contractor may be called upon to assist the study investigator in the case of an emergency, the contractor is not responsible for the health and welfare of the human studies participants. In addition, on-site Contractor biomedical personnel should be certified in CPR techniques.

2. Electrical Safety. The Contractor shall implement procedures found in the Operational Electrical Safety Manual for the Clinical Research Branch, relating to all subject related electrical equipment. Procedures include logging of equipment, testing of electrical receptacles, equipment leakage measurements and ECG safety inspections for all subject areas in the facility. These procedures define a clinically and technically effective electrical safety manual which complies with applicable state codes and the most recent versions of the following documents:

- Health Care Facilities, ANSI/NFPA 99
- National Electrical Code, ANSI/NFPA 70
- Electrical Equipment Maintenance, NFPA No. 70B

The Contractor shall continuously monitor the status of changing electrical safety of medical instrumentation by various manufacturers and new regulations, and shall provide a periodic update of this knowledge to the Agency. Revisions to NFPA 99 shall be provided in updates within 120 calender days of becoming effective. The Contractor shall also perform necessary retrofit maintenance on all systems to ensure conformance to regulations and protection of human test subjects from electrical shock in accordance with manufacturer changes and current federal regulations.

3. Facility Safety. The Contractor shall be responsible for identifying and correcting all instances of non-compliance with OSHA standards.

4. Safety Officer. The Contractor shall designate a single person within its

organization as the Safety Officer. Major responsibilities of the Safety Officer shall include:

- Interface with the EPA Safety Officer
- Preparation of incident reports describing each safety violation
- Conduct twice annual facility inspections to identify possible safety hazards violation
- Oversight of the Contractor's on-site safety program

5. Gas Pollutant Supply. The Contractor shall supply all gas cylinders required to operate the Gas Control System. If available, United States Pharmacopeia (USP) grade gases shall be used for exposure to human subjects. A vendor-certified post-fill analysis of the contents shall be obtained for other pollutant gases purchased for use in human exposures. At least 99.5% of cylinder components shall be accounted for in the analysis.

6. Chemical Pollutant Supply. All chemicals used as a pollutant source shall be accompanied by a Material Safety Data Sheet. No chemical that is a known hazard (class A toxin) at the intended level of exposure is to be used in any of the Human Exposure Chambers.

G. **TASK 5 - UPGRADING OF SYSTEMS**

Using space and facilities on-site at the Human Studies Facility, the Contractor shall maintain shop facilities with a sufficient assortment of machine tools for repair or construction of devices associated with this contract. The Contractor shall also maintain sufficient electronic shop facilities for repair and construction of electronic circuits.

The Contractor shall, upon written approval of the Project Officer, correct all deficiencies in contract related systems. As new techniques, instrumentation, and improved components become available, the Contractor shall upgrade the performance of the systems and build new systems to ensure that the most up-to-date and appropriate equipment available shall be used in human exposure studies.

The Contractor shall provide and use a tracking system for requesting modifications and reporting progress, including costs, schedules and milestones.

In response to documented EPA directions, the Contractor shall recommend changes in design of equipment, instruments, or systems to correct deficiencies or improve performance of the exposure chambers, biomedical systems, or other human testing facilities. Upon written approval by the Project Officer, the Contractor shall implement the changes, including acquisition of new equipment.

The following are examples of the types of tasks the Contractor shall be expected to perform, and examples of equipment and instruments that may require redesign, modification, or replacement with new acquisitions during the term of this contract. This list is by no means all inclusive.

1. System Development and Maintenance

a. Replace current hardware that is difficult to maintain and increasingly inclined to failure with maintainable, reliable new equipment.

b. Make use of improved products in computer technology to reduce

hardware costs.

c. Integrate "off-the-shelf ” hardware/software measurement systems into the human exposure chambers and other systems.

d. Employ common design philosophies when upgrading the biomedical, gas, and aerosol systems to improve compatibility and maintainability.

2. Biomedical System.

a. Upgrade existing ECG telemetry system for compatibility with new FCC channel assignments.

b. Improve distribution of particulate matter in CAPs chambers.

c. Develop systems for conducting exposures to different pollutants.

3. Facilities.

In accordance with documented work orders, the Contractor may be required to design, acquire, and install new equipment or instrumentation not originally present in the Facility. These may include items such as filters, ducts, regulators, controllers and physiological, pollutant monitoring or other devices relating to the safe exposure and measurement of test subjects or biological samples.

H. TASK 6 - SYSTEM DOCUMENTATION AND TECHNICAL REPORTS

The contractor shall maintain the system documents, incorporated by reference in Attachments 3 and 4, and all manuals delivered under Contractor control relating to the systems installed in the Human Studies Facility. All documents and drawings are currently considered accurate.

The contractor shall prepare new documentation describing system additions and modifications. The contractor shall identify and replace outdated documentation and drawings when system modifications are made. As new systems are added, the contractor shall prepare new operation manuals, maintenance manuals, and other documentation necessary to operate and maintain the system.

Occasionally, the Contractor shall be required to prepare the following documents:

1. Technical reports related to work conducted under this contract.
2. Papers to be published in journals. Such papers shall be prepared according to the directions of the specific journal.

These reports shall be published in EPA's Research Reporting Series and shall be prepared in accordance with EPA-600/9-91-004, "Technical Information Policy and Guide of the Office of Research and Development", 1991. These or other papers based in whole or in part on work conducted under EPA contract shall be submitted to EPA for approval prior to submission. Indications of authorship of such reports and articles should be mutually agreed upon on assignment, but will be at the discretion of the EPA Project Officer.

I. PERFORMANCE STANDARDS AND OBJECTIVES

The Quality Assurance Surveillance Plan (QASP) establishes the performance standards, acceptable quality level, method of surveillance and impact on contractor's payments for each of the major service areas of this performance

based work statement. The contractor shall satisfy the performance objectives and payment considerations included in the QASP (See Attachment 5).